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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,917	08/06/2001	Alexander Varshavsky	GPCG-P01-017	9016
28120	7590	08/11/2004	EXAMINER	
ROPE & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			LAMBERTSON, DAVID A	
			ART UNIT	PAPER NUMBER

1636

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/923,917	Applicant(s) VARSHAVSKY ET AL.	
	Examiner David A. Lambertson	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-114 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-114 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3 and 5-12, drawn to a pair of fusion proteins comprising a membrane-associated protein fused to either an N-terminal or C-terminal subdomain of ubiquitin and a reporter moiety, classified in class 530, subclass 350.
- II. Claims 2 and 4-12, drawn to a pair of fusion proteins comprising a transcription factor fused to either an N-terminal or C-terminal subdomain of ubiquitin and a reporter moiety, classified in class 530, subclass 350.
- III. Claims 13 and 14, drawn to isolated nucleic acids encoding fusion proteins comprising a membrane-associated protein fused to either an N-terminal or C-terminal subdomain of ubiquitin and a reporter moiety, classified in class 536, subclass 23.1.
- IV. Claims 15 and 16, drawn to isolated nucleic acids encoding fusion proteins comprising a transcription factor fused to either an N-terminal or C-terminal subdomain of ubiquitin and a reporter moiety, classified in class 536, subclass 23.1.
- V. Claims 17, 19 and 21-39, drawn to a method of detecting interactions between a protein and a membrane-associated protein, classified in class 435, subclass 7.2.
- VI. Claims 18 and 21-39, drawn to a method of detecting an interaction between a protein and a transcription factor, classified in class 435, subclass 7.1.

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- VII. Claims 40-65, drawn to a method of determining an agonist of a protein-protein interaction by measuring an increase in ubiquitin-specific protease cleavage and the resulting degree of reporter activity in the presence of a compound, classified in class 435, subclass 7.1.
- VIII. Claims 40-65, drawn to a method of determining an antagonist of a protein-protein interaction by measuring a decrease in ubiquitin-specific protease cleavage and the resulting degree of reporter activity in the presence of a compound, classified in class 435, subclass 7.1.
- IX. Claims 69-114, drawn to a method and kit for identifying and characterizing the sequence of a protein that binds to a given sequence, classified in class 435, subclass 4.

It is noted that claims 5-12 are present in Groups I and II. These claims are multiply dependent on independent claims relating to independent Groups I and II, as set forth above. Upon the election of a Group, claims 5-12 will be examined with respect to the elected subject matter.

It is noted that claims 21-39 are present in Groups V and VI. These claims are multiply dependent on independent claims relating to independent Groups V and VI, as set forth above. Upon the election of a Group, claims 21-39 will be examined with respect to the elected subject matter.

The inventions are distinct, each from the other because of the following reasons:

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Inventions Group I and Group II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of being used together. Specifically, Group I is related to a fusion protein having a domain with the functional capacity to be a membrane-associated protein, whereas Group II is related to a fusion protein having a domain with the capacity to be a transcription factors. The function of a membrane-associated domain and transcription factor are distinct from each other, therefore the individual fusion proteins having functionally distinct properties. As a result, the Groups represent patentably distinct inventions.

Inventions Group III and Group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions that are not disclosed as capable of being used together. Specifically, Group III is related to a nucleic acid encoding a fusion protein having a domain with the functional capacity to be a membrane-associated protein, whereas Group IV is related to a nucleic acid encoding a fusion protein having a domain with the capacity to be a transcription factor. Because each nucleic acid encodes a protein with a distinct biochemical function, the individual nucleic acids have functionally distinct properties. As a result, the Groups represent patentably distinct inventions.

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Inventions Groups I-II and Groups III-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have distinct functions and are not disclosed as capable of being used together. Specifically, Groups I-II are directed to polypeptide fusions, whereas Groups III-IV are directed to nucleic acids. The function of a nucleic acid is to encode a protein, whereas the function of a polypeptide is to perform a specific biochemical function based on its amino acid sequence, thus the inventions have different functions. As a result, the inventions are patentably distinct from each other.

Inventions Group V and Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and are not disclosed as capable of being used together. Specifically, Group V utilizes a nucleic acid encoding a membrane-associated fusion protein, whereas Group VI utilizes a nucleic acid encoding a transcription factor fusion protein. Because Groups V and VI utilize different functional components in their method steps, the inventions have different modes of operation and are therefore patentably distinct.

Inventions Groups I-II and Groups V-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

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operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and are not disclosed as capable of being used together. Specifically, Groups I-II are related to polypeptide sequences, whereas Groups V-VI make use of nucleic acid sequences. Because the products of Groups I-II cannot be directly used in the methods of Groups V-VI, the inventions are unrelated.

Inventions Group III and Group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a material different process, such as for the production and purification of a membrane-associated protein.

Inventions Group III and Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of being used together. Specifically, the method of Group VI makes use of a nucleic acid encoding a transcription factor fusion protein; however, the product of Group III does not specifically encode such a fusion protein. As such, the inventions have distinct functions, making them patentably distinct from each other.

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Inventions Group IV and Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of being used together. Specifically, the method of Group V makes use of a nucleic acid encoding a membrane-associated protein fusion protein; however, the product of Group IV does not specifically encode such a fusion protein. As such, the inventions have distinct functions, making them patentably distinct from each other

Inventions Group IV and Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a material different process, such as for the production and purification of a transcription factor.

Inventions Group VII and Group VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different effects and are not disclosed as capable of being used together. Specifically, Group VII comprises a method of identifying an agonist (and has the effect of identifying one), whereas Group VIII comprises a method step of identifying an antagonist (and has the effect of finding one). Because the method

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step of identifying an agonist requires the detection of an increase in cleavage, and the method step of identifying an antagonist requires the detection of a decrease in cleavage, these method steps are patentably distinct and produce a different outcome/effect. As such, the inventions are considered patentably distinct.

Inventions Groups V-VI and Groups VII-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different effects. Specifically, Groups VII-VIII are directed to the identification of an agonist/antagonist, respectively, and require a method step for doing so. Groups V-VI require no such step and are not directed to the same outcome, therefore the inventions are considered patentably distinct.

Inventions Groups V-VIII and Group IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different method steps and effects, and are not disclosed as capable of being used together. Specifically, Group IX requires a method step for characterizing a sequence that is identified, a method step that is not required in any of Groups V-VIII. As such the inventions are considered patentably distinct.

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Inventions Groups I-II and Groups VII-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of being used together. Specifically, Groups VII-IX make use of nucleic acid sequences, whereas Groups I-II are related to polypeptide sequences which are not used directly in the methods of Groups VII-IX. Because the products of Groups I-II cannot be directly used in the methods of Groups V-VI, the inventions are unrelated.

Inventions Groups III-IV and Groups VII-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Groups III-IV can be used in materially different processes, such as any of the patentably distinct methods of Groups V-IX, or in the production and purification of a transcription factor or membrane-associated protein.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, especially in instances where the classifications are the same, the non-patent literature searches required for each of these inventions are not co-

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extensive, hence said searches would be burdensome. Therefore restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

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product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.
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JAMES KETTER
PRIMARY EXAMINER